



OVERVIEW OF COMPLIANCE WITH THE AGREEMENT ON TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS (*TRIPS Agreement*) IN ADDRESSING ISSUES CONCERNING PATENT WHICH RELATES WITH COMPETITION LAW: MALAYSIA POSITION



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ABSTRACT

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Malaysia.

TRIPS Agreement acknowledged that some licensing restrictions contained in a patent license contract may contravene the principles of competition law. Hence, adoption of appropriate measures to address issues concerning patent license which relates with competition law has been expressly provided by the TRIPS Agreement in its various provisions. Malaysia as a signatory of the TRIPS Agreement is expected to comply with the recommendations in addressing issues concerning patent license and competition law. Therefore, it is the purpose of this article to identify extends of compliance by Malaysia with respect to the suggestions provided by the TRIPS Agreement. The result shows that Malaysia adopts the recommendations provided by the TRIPS Agreement in its legislation, particularly the Patents Act 1983.

Contribution/ Originality: This study contributes in the existing literature on patent and competition law as a result of a new law introduced by the Malaysian government known as the Competition Act 2010 and the recent Malaysia Competition Commission (MyCC) Guidelines on Intellectual Property Rights and Competition Law.

1. INTRODUCTION

Restrictions contained in a patent license may contravene the principles of competition law because the exercising of rights by patent owners is monitored by laws other than the patent law, such as the competition law (Stakheyeva, 2018). As a result, scholars such as Michael (2002), Hovenkamp (2013), Ioannis (2017) and Gregory (2018) have pointed out factors contributing to it and provide recommendations to solve the issue. The problem had also been discussed at the initial drafting of the TRIPS Agreement during the Uruguay Round so that signatories of the TRIPS Agreement were aware on the issues surrounding intellectual property. The TRIPS Agreement, which is one of the World Trade Organizations' (the WTO) document came into existence as a result of Uruguay Rounds negotiations which was held under General Agreement on Tariffs and Trade (GATT) (WIPO, 1997). Council for Trade-Related Aspects of Intellectual Property Rights under the WTO is assign to manage the operation of TRIPS Agreement (Adamantopoulos, 1997). The WTO Agreements generally provides basic rules to be adhered by governments in framing their domestic policies and practices in the following areas; international trade in goods and services and intellectual property rights. Some examples of WTO Agreements include the Multilateral

Agreements on Trade in Goods, Agreement on Trade in Services and Agreement on Trade-related Intellectual Property Rights (Bhagirath, 1998). According to Peter *et al.* (2017) majority of ASEAN member states have acceded to international conventions and treaties relating to intellectual property including the TRIPS Agreement while Malaysia is a signatory to the TRIPS Agreement since 1995.

Alison (2016) provides a comprehensive study on the TRIPS Agreement focusing on Article 7 and 8 of the said Agreement. Alison was of the view that Article 8.2 of the TRIPS Agreement which provides freedom to signatories to provide laws and measures necessary to prevent abuse of intellectual property rights is a “balance between intellectual property protection and competition rules.” The uniqueness is that, issues may be resolved at national level without the need to be dictated by the TRIPS Agreement because the TRIPS Agreement does not specify in detailed abusive practices and what measures should be employed by the signatories. It is therefore, according to Alison that TRIPS Agreement gives way to national policy makers to design their own laws so that it fits with the local conditions and circumstances. However, appropriate measures designed by the nationals must comply with the provisions contained in the TRIPS Agreement.

Cynthia (2016) argued that at present, WTO member countries have limited freedom to design their intellectual property laws due to the fact that they are required to comply with the minimum standards of intellectual property rights provided by the TRIPS Agreement. Although such compliance is only to the “minimum standards” and not “uniform standards”, the TRIPS Agreement failed to define the key minimum standards, leaving it to the discretion of the member countries to decide the terms. As a result, terms have been defined differently, which, according to Cynthia a situation which exists prior to the TRIPS Agreement and will continue to be practiced even during the presence of TRIPS Agreement.

Mark (2016) and David (2019) viewed TRIPS Agreement as compromises between developed and developing countries particularly in the area of patent system. According to Mark (2016) the TRIPS Agreement provide flexibilities to developing countries to use their domestic legislations to take “appropriate measures consistent with the TRIPS Agreement” to prevent abuse of intellectual property and also anti-trust issues. David (2019) pointed out that enforcement of patents, specifically provision on compulsory license is one of the examples of compromises made by the TRIPS Agreement between developed and least-developed countries in order to ensure that balance is reached between them especially in respect of access to medicines.

In respect of compliance with provisions contained in the TRIPS Agreement, extensive discussion have been made in the said area. Amongst the recent studies are by Darya (2016), Nurul (2017) and Chowdhury (2018).

Darya (2016) investigated compliance of China with the principles contained in Article 41 and Article 63 of the TRIPS Agreement. Darya further argued that China has indeed failed to implement principles enshrined under Article 41 of the said Agreement and also the transparency requirements under Article 63 of the same Agreement. Nurul (2017) also speaks about compliance with the provisions in TRIPS Agreement by ASEAN member states in general but emphasize is given to the ASEAN framework in respect of intellectual property law development at the ASEAN level. Chowdhury (2018) also provides discussion on compliance of TRIPS Agreement by Bangladesh with specific focus on the enforcement of intellectual property laws in Bangladesh.

On the other hand, Kassor (2018) investigated factors which contributed to the difficulty to comply with the TRIPS Agreement among developed and least developed countries. Based on his studies, it was found that, those countries were not well presented during the Uruguay Round and high costs is needed by those countries to set up an effective intellectual property system as required by the TRIPS Agreement.

Hence, based on the literature above, it was found that discussion on TRIPS Agreement compliance by Malaysia in addressing issues concerning patent which relates with competition law has not been discussed by earlier scholars. It is therefore that this paper is relevant to fill in the gaps in the literature.

As such, this paper begins its discussion on the TRIPS Agreement by highlighting provisions concerning patent license which relates with competition law. It was then followed by an analysis of compliance by Malaysia on

provisions relating to patent license which relates with competition law contained in the TRIPS Agreement. The analysis also includes evidences of provisions on the related area in the domestic legislations, such as the Patents Act 1983 and the Competition Act 2010. This paper provides a conclusion on whether or not Malaysia has complied with the recommendations set by the TRIPS Agreement concerning issues surrounding patent license which relates with competition law

2. THE TRIPS AGREEMENT

TRIPS Agreement is made up of principles derived from Paris Convention and Berne Convention. Most of the provisions embodied in both Conventions are incorporated into TRIPS Agreement, for example, Article 9 (1) of TRIPS agreement which necessitate signatories to adhere with Article 1 to 21 of Berne Convention. As one of the WTO Agreements, the TRIPS Agreement aims at providing a convenient international trade environment as reflected in the following preamble:

“Desiring to reduce distortions and impediments to international trade, and taking into account the need to promote effective and adequate protection of intellectual property rights, and to ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade...”

Based on the preamble of the TRIPS Agreement, it seeks to achieve two main objectives, which are; to minimize distortions and barriers to international trade and to protect intellectual property rights. The core principle relating to the said Agreement is that Members are compulsory to give effect to the clauses contained in the TRIPS agreement. However, since TRIPS agreement only provides general legal framework relating to intellectual property matters, members are given the freedom to decide the implementation mechanism based on their national laws.

The TRIPS Agreement contain seven areas which relates to intellectual property, namely, copyright, trademarks, geographical indication, industrial design, patents, layout designs of integrated circuits and undisclosed information. Generally, the TRIPS Agreement is aware of the fact that patent owners are capable of abusing their patent rights via licensing which may harm the competition in the market. Based on Article 8.2 of Part I of the TRIPS Agreement, the TRIPS Agreement permit members of the TRIPS Agreement to take proper measures in the following matters:

- (i) Preventing abuse of intellectual property rights.
- (ii) Practices which unreasonably restrain trade.
- (iii) Adversely affect the international transfer of technology, provided such measures are in accordance with the provisions of the TRIPS Agreement.

Abuse or misuse of patent rights by patent owners may result to infringement of competition law due to restrain of fair competition in the market.

The above Article 8.2 of the TRIPS Agreement is further strengthened by Article 40.2 of Part II of section 8 of the TRIPS Agreement which allows signatories of the TRIPS Agreement to “specify practices which constitute abuse of intellectual property rights” in their respective legislations. Some of the practices which are calculated as abuse of intellectual property rights are exclusive grant back provision, provision relating to challenging validity of intellectual property as well as package licensing. These conducts were as a result of licensing practices indicated by the TRIPS Agreement under Article 40.2.

Apart from the abovementioned provisions, matters relating to compulsory license is addressed under Article 31 of the TRIPS Agreement. Article 31 of the TRIPS Agreement allows “the practice of compulsory license by the government or third parties empowered by the government, provided provisions such as non-exclusive compulsory license, adequate remuneration or non-assignable under Article 31 (a) to (l) shall be respected.”

Another area highlighted by the TRIPS Agreement is on the issue of exhaustion of intellectual property rights. Based Article 6 of the TRIPS Agreement, it expressly provides that “for the purpose of dispute settlement process,

nothing in the TRIPS Agreement will be used to address the issue of the exhaustion of intellectual property rights.” The provision in the said Article is an indication that the TRIPS Agreement will not entertain complaints relating to matters involving exhaustion of intellectual property rights. Patent owners are commonly given the rights to make, sell, distribute and import the patented goods. In the event the protected goods have been placed in the market by a distributor who has contractual agreement with the patent owner, the patent owner is prevented from taking infringement action if the patented goods are imported beyond the agreed distribution area. This is referred to as an exhaustion of rights by patent owners.

Exhaustion of intellectual property rights may occur in the following situations, which are; international, regional and national exhaustion. International exhaustion relates to situation where the rights will be exhausted irrespective of where the product was placed in the market, which means that the intellectual property owner has no right to block parallel import. For example in Malaysia, an owner of a patent is said to have exhausted his rights once the patented product is put on the market regardless whether such market is within or outside Malaysia. In contrast, national exhaustion refers to the system in which the rights will not be exhausted if the product was put on the market outside the jurisdiction. For example, a patent owner in the United States of America (US) may sue for infringement if the patented product is brought to the US market without the patent owner having his first right to market such patented product within the United States. Regional exhaustion refers to the rights which will be exhausted if the products are placed in the market within the region. In such a situation, the intellectual property owner remains the right to stop parallel import from outside the region (Stothers, 2007). This may be the case in the European Union (EU) region whereby a patent owner rights is exhausted once the patented product is placed in any of the market in the EU.

Hence, it can be summarized that the TRIPS Agreement allows the following actions to be taken by member countries in relation to patent and competition law; (i) to set up appropriate measures in preventing misuse of intellectual property rights (ii) to allow compulsory license (iii) to adopt rules for exhaustion of intellectual property rights.

3. ANALYSIS OF COMPLIANCE WITH THE TRIPS AGREEMENT: MALAYSIA POSITION

Based on the discussion above, the following seeks to analyse the extent of compliance by Malaysia with respect to the TRIPS Agreement.

(i) To set up appropriate measures in preventing misuse of intellectual property rights.

As discussed earlier, the TRIPS Agreement permits inclusion of provisions relating to misuse of intellectual property rights in domestic legislations. This is reflected in section 45 of the Patents Act 1983 which provides on invalid clauses of a patent license contract. According to the said provision, clauses included in the licence will be invalid if it imposes restrictions in the industrial or commercial field which are “not derived from the rights conferred by this Part on the owner of the patent.” Granting either exclusive or non-exclusive license is within the rights of a patent owner. Apart from that, the granting of exclusive or non exclusive license enables the patent owner to grant the following acts to be performed by the licensee under section 36(3) of the Patents Act 1983; which are the right to:

- (i) Make, import, offer for sale, sell or use the product.
- (ii) Stocking such product for the purpose of offering for sale, selling or using if the patented invention is a product and (i) using the process or (ii) making, importing, offering for sale, selling or using the product (in respect of a product obtained directly by means of the process).

Section 45 of the Patents Act 1983 provides that the following shall not be considered as restrictions not within the rights of a patent owner, which are:

- (i) Limitation on the scope or duration to exploit the patented invention.
- (ii) Territorial limitation.

- (iii) Limitation on the quality or quantity of the products.
- (iv) Limitation imposed to the licensee from challenging the validity of the.

Impliedly, it can be said that section 45 of the Patents Act 1983 considers that the above restrictions are within the rights granted by the Patents Act 1983 to patent owners. Restriction concerning the scope of the patented invention relates to the field of use restriction as commonly included in a patent license contract. Such restriction is permitted by the Patents Act 1983 and is recognized as within the rights conferred by the Patents Act 1983 to the patent owner. This is qualified by section 43(1) of the Patent Act 1983. Although section 43(1) of the Patents Act 1983 provides that the licensee has the right to perform all acts under section 36(3) and 36(1)(a), "within the geographical area of Malaysia without limitation as to time and through any application of the invention," section 43(1) of the Patents Act 1983 emphasizes that it is subject to the "absence of any provision to the contrary in the license contract." This means that, in the event the licensor in the license contract limits the usage of the patented products to a specific field of commercial use within a specific period, therefore, it is a valid provision in the patent license contract because the Patents Act 1983 recognizes such restrictions as within the rights of a patent owner.

Restriction concerning the geographical area or commonly known as territorial restriction is also expressly permitted by the Patents Act 1983. The imposition of such restriction to a licensee is supported by section 43(1) of the Patents Act 1983 when it provides that "in the absence of provision to the contrary in the patent license contract, the licensee shall be entitled to do any acts described in section 36(1) (a) and section 36(3) of the Patents Act 1983 within the whole geographical area of Malaysia without limitation as to time and through any application of the invention." Thus, territorial restriction is permissible to be imposed to a licensee in a patent license contract according to the Patents Act 1983.

Restriction on the quality or quantity of the products produced in relation to the patented invention is expressly permitted by the Patents Act 1983. Restriction on the quantity may be seen as output restriction as commonly inserted in a patent license contract. Output restriction aims to limit the quantity of products produced using the patent invention, which may be in the form maximum quantity restriction or minimum quantity restriction.

Obligations which impose upon the licensee to abstain from all acts capable of prejudicing the validity of the patent under section 45(b) of the Patents Act 1983 suggests that a licensor may impose on the licensee not to challenge the validity of the patented invention in the license contract. This indicates that the Patents Act 1983 permits the inclusion of such clause in a patent licence contract. Further, by virtue of section 61(2) of the Patents Act 1983, it provides that "in the event that there are any infringement proceedings indicated by the licensee, the licensee may request the owner of the patent to institute court proceedings." The licensee is prevented from instituting any infringement proceedings on its own except, if the licensee is able to prove that even though the patent owner receives the request, the patent owner refuses or fails to take action within three months. In such a case, the licensee may on its own institute the proceedings in his own name provided that notification of the licensee's intention has been made to the patent owner. The owner shall have the right to join in the proceedings even though it has been instituted by the licensee. However, the right to institute infringement proceedings is subject to subsection (1) of section 61 which provides that "...unless the license contract provides that the provisions of this subsection do not apply or provides different provision," indicating that the right to exercise infringement proceedings depends on the agreed terms in the license contract between the licensor and the licensee.

Summarily, it can be said that restrictions contained in the section 45 of the Patents Act 1983 are in fact list of valid clauses which are permitted to be incorporated in a patent license contract. The TRIPS Agreement provides sample of clauses which may have adverse effect on the competition such as, exclusive grant back provision, provision relating to challenging validity of intellectual property and package licensing. Grant back provision and package licensing have not been addressed by the Patents Act 1983 but incorporation of a clause prohibiting a licensee challenging the validity of an intellectual property is expressly permitted by the

Patents Act 1983. In addition, an official Guideline on Intellectual Property for Competition Law has been issued by the Malaysia Competition Commission on April 2019 which provides clarification in this area.

(ii) To allow compulsory license.

Compulsory license means authorisation to perform any exclusive rights of the patent owner without patent owner permission. This is provided by section 48 of the Patents Act 1983 which impliedly provides no obligation to the patent owner to license his patented invention. The situations in which compulsory license may be requested rely on the following reasons as mentioned in section 49 of the Patents Act 1983:

- (a) The non-existence of the said patented product or process in Malaysia without any legitimate reason.
- (b) The product produced under the patent is not available for sale in Malaysia or any domestic market, or there are some but they are sold at unreasonably high prices or do not meet the public demand without any legitimate reason.
- (c) Efforts have been made by the person making the application of compulsory license to obtain authorisation from the owner of the patent on reasonable commercial terms and conditions but was not successful.
- (d) Where it is determined by the Government that there is national emergency or it is in the public interest, such as national security, nutrition, health or the development of other vital sectors of the national economy.
- (e) Where a judicial or relevant authority has determined that the manner of exploitation by the patent owner or his licensee is anti-competitive.

The first three reasons mentioned above may be requested by any person to the Registrar for the purpose of compulsory license while the remaining two reasons are rights given to the Government agency or a third party to exploit a patent without consent of the patent owner. For example, the Malaysian government decided to issue compulsory license on 29th October, 2003 after several negotiations for reduction of price for drugs necessary for AIDS treatment failed. As a result, local company is allowed to import the said drug which was patented by GlaxoSmithKline and Bristol-Myers Squibb. The authorization of compulsory licensing was valid for two years and several conditions were made, such as the medicines be tagged with the word "Ministry of Health Malaysia" and royalties need to be paid to the patent holder(s) within two months of importation of each successive batch. The authorization expired on 1 November 2005.

Another example of a recent case on compulsory license takes place in 14th September, 2017 in which the Malaysia government decided to issue compulsory license to import medicines for Hepatitis C treatment. The decision to issue compulsory license by the Malaysian cabinet implies that the medication can be produced without the patent holders' consent and at a cheaper price. It is pertinent to mention that the above cases fall within the ambit of "Government use" expressly provided under section 84 of the Patents Act 1983 and not based on the Competition Act 2010.

Apart from that, compulsory license may be issued as a result of interdependence of patents. By virtue of section 49A of the Patents Act 1983, if invention in a later patent cannot be worked in Malaysia without infringing earlier patent, the Intellectual Property Corporation of Malaysia (MyIPO) may grant compulsory license to the extent necessary for the purpose of avoiding infringement of the earlier patent. However, the granting of compulsory license is subject to the opinion of the MyIPO that the later patent forms "important technical advance of considerable economic significance in relation to the invention claimed in the earlier patent."

The above discussion relating to compulsory license in Malaysia suggests that compulsory licensing may be applied due to various reasons, which are as follows; absence of production of the patented product in Malaysia, adequacy of the supply of the patented product in Malaysia, efforts to obtain consent from the patent owner based on reasonable reasons have not been successful, public interest and the exploitation of the patent is anti-competitive.

Therefore, it can be said that provisions concerning compulsory license as contained in the Patents Act 1983 conforms to the TRIPS Agreement.

(iii) To adopt rules for exhaustion of intellectual property rights.

In Malaysia, parallel import is allowed based on the provisions contained in section 37(2) and section 58A of the Patents Act 1983. Section 37 (2) and section 58A suggests that a patent owner is prevented from claiming that an infringement of patent has occurred if the product which relates to the patent has been put to market in the following situations:

“(i) Product put to market with the consent of the patent owner.

(ii) Product put to market by the following person; (a) the patent owner (b) a person having the right despite the grant of patent to exploit the patent under section 38 of the Patents Act (1983) (c) the licensee under section 43 of the Patents Act 1983 (d) the beneficiary of the compulsory license under section 48 of the Patents Act (1983).

By virtue of section 37 (2) of the Patents Act (1983) it expressly provides that the rights under the patent “shall not extend to acts in respect of products which have been put to market by the owner of the patent, or by person having the rights referred to in section 38, section 43 and section 48 of the Patents Act (1983).” The “rights under the patent” as indicated by the section 37 (2) of the Patents Act (1983) refers to the “rights to make, import, offers for sale, selling or using the patented product.”

A patent owner referred to in section 37(2) of the Patents Act (1983) relates to “a person who owns the patent” while section 38 of the Patents Act (1983) refers to “a person who has the right to exploit the patent” despite the grant of the patent due to the following reasons:

(i) The person at the priority date of patent application was in good faith make the product or use the invention (which is the subject of the invention claimed in the application) in Malaysia.

(ii) The person at the priority date of the patent application had in good faith in Malaysia made serious preparations towards the making of the product or process.

On the other hand, licensee as referred to in section 43 of the Patents Act (1983) refers to the rights of the licensee to perform acts as indicated under section 36(1) (a)–(c) and section 36(3) (a)-(b) of the Patents Act (1983) while beneficiary of the compulsory license provided under section 48 of the Patents Act (1983) refers to “person whom a compulsory license has been granted in accordance with Part X (on compulsory license)” of the Patents Act (1983).

Another provision which supports the fact that parallel import is permitted under the patent law in Malaysia is based on section 58A of the Patents Act (1983). According to section 58A of the Patents Act 1983, “any patented product which is produced with the consent (conditional or otherwise) of the owner of the patent or licensee shall not be considered as an act of infringement to import, offer to sale, sell or use of the patented product or process.” It indicates that any reproduction of a patented product by any person and consented by the patent owner or licensee is not an infringement offence under the Patents Act (1983). Such consent, according to section 58A of the Patents Act (1983) may be “conditional or unconditional.” Conditional consent relates to the fact that the patent owner imposed restriction to the other party from reselling the patented product beyond the territory of manufacture. Unconditional consent relates to situation in which the patent owner is silent on the resale of the patented products beyond the territory of manufacture. In both situations, the Patents Act (1983) considers that the act of resale of the patented product beyond the territory of manufacture is not an act of infringement. This is due to the fact once the patented product has been put on the market elsewhere by the patent owner, the patent owner is regarded as giving an implied consent for the resale of the patented product beyond the territory of manufacture.

Thus, it can be said that the Patents Act 1983 supports parallel import via expressed provisions provided under the said Act. The provisions in the Patents Act (1983) also suggest that Malaysia adopts international exhaustion doctrine since the Patents Act (1983) is silent on the identification of market which applies for the purpose of parallel import. Hence, it can be said that in Malaysia, parallel importation is allowed and not prevented. The fact that the TRIPS Agreement is silent in respect of a specific exhaustion of intellectual property rights to be adopted by member countries indicate that Malaysia is free to adopt any kind of exhaustion of intellectual property rights.

4. CONCLUSION

The above discussion shows that the recommendation of the TRIPS Agreement to set up measures for prevention of abuse of intellectual property rights has been indicated by the Malaysia Patents Act 1983 and the Competition Act 2010. Apart from that, the permission given by the TRIPS Agreement to exercise compulsory license by member countries can be clearly seen when the Patents Act (1983) provides specific provisions relating to compulsory license. Besides that, the provisions in the Patents Act (1983) has been carried out into practice when the Malaysian government exercise compulsory license in relation to patents owned by GlaxoSmithKline and Bristol-Myers in 2003 and also in 2017 in relation to medicines for Hepatitis C treatment. However, it remains to be seen the issuance of compulsory license on the basis of anti-competitive behavior of patent owners as contained in the Patents Act (1983). In addition, although suggestion by the TRIPS Agreement to adopt rule on exhaustion of intellectual property rights remains brief and general, Malaysia has taken steps to ensure it is addressed adequately in the Patents Act (1983). The Patents Act (1983) provides various provisions to indicate that international patent exhaustion is the approach adopted by Malaysia. Therefore, it can be said that Malaysia complies with all the recommendations set by the TRIPS Agreement in relation to addressing issues concerning patent which relates with the competition law.

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